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|---|---|---|--|--|
| FORM PTO-1390<br>(REV 10-94)  |   | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE |  | ATTORNEY'S DOCKET NUMBER<br>11123.0108USWO                             |
| TRANSMITTAL LETTER TO THE UNITED STATES<br>DESIGNATED/ELECTED OFFICE (DO/EO/US)<br>CONCERNING A FILING UNDER 35 U.S.C. 371  |   |   |  | U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5)<br><b>10/586801</b> |
| INTERNATIONAL APPLICATION NO.<br>PCT/EP2005/001524  | INTERNATIONAL FILING DATE<br>January 24, 2005 | PRIORITY DATE CLAIMED<br>January 23, 2004               |  |  |
| TITLE OF INVENTION<br>PHARMACEUTICAL FORMULATIONS COMPRISING METFORMIN AND A FIBRATE, AND PROCESSES FOR OBTAINING THEM  |   |   |  |  |
| APPLICANT(S) FOR DO/EO/US<br>DAWSON et al.  |   |   |  |  |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:   |   |   |  |  |
| <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>3. <input checked="" type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(I).</li> <li>4. <input type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.</li> <li>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau).</li> <li>b. <input checked="" type="checkbox"/> has been transmitted by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US)</li> </ol> </li> <li>6. <input type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2)).</li> <li>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau).</li> <li>b. <input type="checkbox"/> have been transmitted by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input checked="" type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input checked="" type="checkbox"/> A signed oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).</li> <li>10. <input type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li> </ol> |   |   |  |  |
| <b>Items 11. to 16. below concern document(s) or information included:</b>  |   |   |  |  |
| 11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98, Form 1449, 3 references.  |   |   |  |  |
| 12. <input checked="" type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.   |   |   |  |  |
| 13. <input type="checkbox"/> A FIRST preliminary amendment.<br><input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.   |   |   |  |  |
| 14. <input checked="" type="checkbox"/> A substitute specification.   |   |   |  |  |
| 15. <input type="checkbox"/> A change of power of attorney and/or address letter.   |   |   |  |  |
| 16. <input checked="" type="checkbox"/> Other items or information: Application Data Sheet 3 pages, Formal Drawings 2 pages, Marked-Up Copy of Specification, International Publication WO 2005/070396 A1, Form PCT/IB/301, Form PCT/IB/304, Form PCT/IB/308, Form PCT/ISA/210, Form PCT/ISA/220, Form PCT/ISA/237  |   |   |  |  |

|   |              |   |            |  |               |
|---|--------------|---|------------|--|---------------|
| U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5)<br>Filed here <b>10/586801</b>   |              | INTERNATIONAL APPLICATION NO.<br>PCT/EP2005/001524                            |            | ATTORNEY'S DOCKET NUMBER<br>11123.0108USWO   |               |
| <b>BASIC NATIONAL FEE (37 CFR 1.492(a) (1)-(5)):</b>  |              |   |            |  |               |
| [X] a) Basic National fee.....\$300.00  |              |   |            | <b>\$300.00</b>  |               |
| [X] b) Examination fee.....\$200.00   |              |   |            | <b>\$200.00</b>  |               |
| [X] c) Search fee.....\$500.00  |              |   |            | <b>\$500.00</b>  |               |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>  |              |   |            | <b>\$1,000.00</b>  |               |
| Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. |              |   |            |  |               |
| Total Sheets  | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | Rate       |  |               |
| 44 • -100 =   | 0 /50 =      |   | X \$250.00 | <b>\$0.00</b>  |               |
| Surcharge of <b>\$130.00</b> for furnishing the oath or declaration later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).  |              |   |            | <b>\$0.00</b>  |               |
| CLAIMS  | NUMBER FILED | NUMBER EXTRA  | RATE       |  |               |
| Total claims  | 23 -20 =     | 3   | X \$50.00  | <b>\$150.00</b>  |               |
| Independent claims  | 2 -3 =       | 0   | X \$200.00 | <b>\$0.00</b>  |               |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable)   |              |   | + \$360.00 | <b>\$0.00</b>  |               |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>  |              |   |            | <b>\$1,150.00</b>  |               |
| Reduction by 1/2 for filing by small entity, if applicable. Small entity status is claimed pursuant to 37 CFR 1.27  |              |   |            | <b>\$0.00</b>  |               |
| <b>SUBTOTAL =</b>   |              |   |            | <b>\$1,150.00</b>  |               |
| Processing fee of <b>\$130.00</b> for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(f)).   |              |   |            | + <b>\$0.00</b>  |               |
| <b>TOTAL NATIONAL FEE =</b>   |              |   |            | <b>\$1,150.00</b>  |               |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property  |              |   |            | + <b>\$40.00</b>   |               |
| <b>TOTAL FEES ENCLOSED =</b>  |              |   |            | <b>\$1,190.00</b>  |               |
|   |              |   |            | Amount to be: refunded   | <b>\$0.00</b> |
|   |              |   |            | charged  | <b>\$0.00</b> |
| a. [X] Check(s) in the amount of <u>\$1,150.00, \$40.00</u> to cover the above fees is enclosed.  |              |   |            |  |               |
| b. [ ] Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.<br>A duplicate copy of this sheet is enclosed.   |              |   |            |  |               |
| c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>13-2725</u> .   |              |   |            |  |               |
| <b>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</b>                                  |              |   |            |  |               |
| SEND ALL CORRESPONDENCE TO:<br>Gregory A. Sebald<br>MERCHANT & GOULD<br>P.O. Box 2903<br>Minneapolis, MN 55402-0903   |              |   |            |  |               |
|   |              |   |            | SIGNATURE:  |               |
|   |              |   |            | NAME: Gregory A. Sebald  |               |
|   |              |   |            | REGISTRATION NUMBER: 33,280  |               |

10/586801

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IAP11 Rec'd PCT/PTO 21 JUL 2006

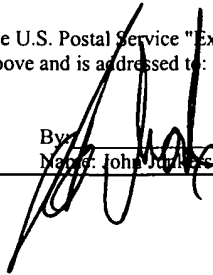
Applicant: DAWSON et al.  
 Docket: 11123.0108USWO  
 Title: PHARMACEUTICAL FORMULATIONS COMPRISING METFORMIN AND A FIBRATE,  
 AND PROCESSES FOR OBTAINING THEM

## CERTIFICATE UNDER 37 CFR 1.10:

"Express Mail" mailing label number: EV 841294615 US

Date of Deposit: July 21, 2006

I hereby certify that this paper or fee is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop: PCT, Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450.

By:   
 Name: John J. Hulse

Mail Stop PCT  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450

Sir:

We are transmitting herewith the attached:

- ☒ Transmittal sheet, in duplicate, containing Certificate under 37 CFR 1.10.
- ☒ National Stage PCT Patent Application for PCT/EP2005/001524, Substitute Specification: Spec. 37 pgs; 23 claims; Abstract 1 pgs.

The fee has been calculated as shown below in the 'Claims as Filed' table.

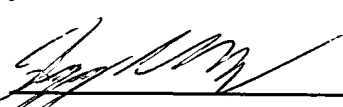
- ☒ 2 sheets of formal drawings
- ☒ A signed Combined Declaration and Power of Attorney
- ☒ Assignment of the invention to Fournier Laboratories Ireland Limited, Recordation Form Cover Sheet
- ☒ A check in the amount of \$1,150.00 to cover the Filing Fee
- ☒ A check for \$40.00 to cover the Assignment Recording Fee.
- ☒ Information Disclosure Statement, Form 1449, 3 reference(s).
- ☒ Application Data Sheet, 3 pages.
- ☒ Form 1390
- ☒ Other: Marked-Up Copy of Specification, International Publication WO 2005/070396 A1, Form PCT/IB/301, Form PCT/IB/304, Form PCT/IB/308, Form PCT/ISA/210, Form PCT/ISA/220, Form PCT/ISA/237
- ☒ Return postcard

## CLAIMS AS FILED

| Number of Claims Filed        | No. | In Excess of | Extra | Rate       | Fee        |
|-------------------------------|-----|--------------|-------|------------|------------|
| Total Claims                  | 23  | 20           | 3     | \$50.00 =  | \$150.00   |
| Independent Claims            | 2   | 3            | 0     | \$200.00 = | \$0.00     |
| Multiple Dependent Claims Fee |     |              |       | =          | \$0.00     |
| Basic Filing Fee              |     |              |       | =          | \$300.00   |
| Search Fee                    |     |              |       | =          | \$500.00   |
| Examination Fee               |     |              |       | =          | \$200.00   |
| Utility Application Size Fee  | 44  | 100          | 0     | \$250.00 = | \$0.00     |
| Total                         |     |              |       | =          | \$1,150.00 |

Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725. A duplicate of this sheet is enclosed.

Merchant & Gould P.C.  
 P.O. Box 2903 Minneapolis, MN 55402-0903  
 612.332.5300

By:   
 Name: Gregory A. Sebal  
 Reg. No.: 33,280  
 Initials: GAS/ncb

23552

PATENT TRADEMARK OFFICE

PTO TRANSMITTAL - NEW FILING)